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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,874	01/30/2004	Mary S. Cupp	35721/273617 (5721-4D)	8052

826 7590 10/20/2004

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,874	CUPP ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10 are pending.

2. Applicant's election with traverse of Group 1, Claims 1-9 drawn to a method for treating a wound in a mammal by administering an amino acid sequence which is at least 90% identical to the mature form of the amino acid sequence of SEQ ID NO: 2, filed 7/30/04, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claim 10 is withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 1-9, drawn to a method for treating a wound in a mammal by administering an amino acid sequence which is at least 90% identical to the mature form of the amino acid sequence of SEQ ID NO: 2, are being acted upon in this Office Action.

5. Applicant should amend the first line of the specification to update the relationship between the instant application and 10/218,699, filed 8/14/02, which is now Pat No. 6,749,855.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for a method of inducing vasodilatation to promote wound healing comprising administering a protein comprising SEQ ID NO: 2, **does not** reasonably provide enablement for a method to treat all wound such as surgical wound or "wound as a result of heart failure" in all mammal such as human comprising administering a therapeutically effective amount of any protein comprising all amino acid sequence which is "at least 90%" or "at least 95%" identical to or amino acid sequence which is the "mature form" of the amino acid sequence

of SEQ ID NO: 2 wherein the protein promotes wound healing as set forth in claims 1-9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a method of producing polypeptide comprising SEQ ID NO: 2 via baculovirus expression system. The recombinant *Simultium vittatum* salivary gland erythema protein (rSVEP) comprising SEQ ID NO: 2 exhibits vasodilative activity when injected into rabbit (Figure 1).

The specification does not adequately teach how to treat all wound such as surgical wound or "wound as a result of heart failure" in all mammal such as human comprising administering a therapeutically effective amount of any protein comprising all amino acid sequence which is "at least 90%" or "at least 95%" identical to or amino acid sequence which is the "mature form" of the amino acid sequence of SEQ ID NO: 2 wherein the protein promotes wound healing.

There is insufficient guidance as to the structure of the "mature form" of SEQ ID NO: 2 without the amino acid sequence. Further, there is insufficient guidance as how to make any protein that is at least 90% or 95% identical to the undisclosed "mature form" of SEQ ID NO: 2. Even if the mature form of the protein is SEQ ID NO: 2, a protein having at least 90% identity means at least 10% difference, which is equivalent to having at least 15 amino acids substitution, deletion, addition and/or combination thereof in SEQ ID NO: 2. There is insufficient guidance as to which amino acids within the full-length polypeptide of SEQ ID NO: 2 could be modified by deletion, addition and/or substitution and whether the resulting modified protein maintain its structure and vasoactive function, in turn, would be useful for the claimed method. Likewise, the same reasoning applies to the method wherein the protein comprises an amino acid sequence which is at least 95% identical to the mature form of the amino acid sequence of SEQ ID NO: 2.

Attwood *et al* teaches that protein function is context-dependent; the state of the art of making functional assignments merely on the basis of some degree of similarity between sequences and the current structure prediction methods is unreliable and knowing structure alone will not inherently tell us function (See figure, entire document).

Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure/function will require guidance (See Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495).

Even if the protein is the amino acid sequence of SEQ ID NO: 2, there are insufficient working examples demonstrating that said protein could treat *all* wound such as surgical wound and "wound as a resulted of heart failure" in all mammal such as human.

In view of the lack of predictability of the art to which the invention pertains, the lack of established protocol for using vasodilator from black fly as a treatment for wound, undue experimentation would be required to practice the claimed method with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed method and absent working examples providing evidence which is reasonably predictive that the claimed method is effective for treating all wound such as wound as a result of heart failure in human.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

8. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of all protein comprises any amino acid sequence which is at least 90% or at least 95% identical to the mature form of the amino acid sequence of SEQ ID NO: 2 for the claimed method.

The specification discloses only a method of producing polypeptide comprising SEQ ID NO: 2 via baculovirus expression system. The recombinant *Simultium vittatum* salivary gland erythema protein (rSVEP) exhibits vasodilative activity.

There is inadequate written description about the structure associated with function of the "mature form" of SEQ ID NO: 2 for the claimed method. Let alone all protein comprises any amino acid sequence which is at least 90% or at least 95% identical to the mature form of the amino acid sequence of SEQ ID NO: 2 without the amino acid sequence for a method to treat all wound such as surgical wound or "wound as a result of heart failure" in all mammal such as human. Even if the mature form of the protein is SEQ ID NO: 2, a protein having at least 90% identity means at least 10% difference, which is equivalent to having at least 15 amino acids substitution, deletion, addition and/or combination thereof in SEQ ID NO: 2. Thus the structure associated with function of all protein comprises any amino acid sequence which is at least 90% or at least 95% identical to the mature form of the amino acid sequence of SEQ ID NO: 2 is not adequately described.

The specification discloses only one protein comprising SEQ ID NO: 2 for a method of inducing vasodilatation to promote wound healing, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of protein to describe the genus for the claimed method. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398; University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC2004).*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

11. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 15, 2004

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